

COMMITTEE REPORT ON THE RETENTION AND USE OF RESIDUAL DRIED BLOOD SPOT SPECIMENS AFTER NEWBORN SCREENING

CURRENT THOUGHTS-DRAFT IDEAS

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Chair, Advisory Committee on Heritable Disorders in Newborns and Children

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Recommendation 1

All state newborn screening programs should have a policy in place that has been reviewed by the state attorney general or other appropriate legal authority addressing the disposition of dried blood specimens remaining after newborn screening.

Recommendation 2

All state newborn screening programs should have a policy in place that has been reviewed by the state attorney general or other appropriate legal authority that specifies who may access and use dried blood specimens once they arrive at the state-designated newborn screening laboratory, including further access after newborn screening tests are completed.

Recommendation 3

All state newborn screening programs should work proactively to ensure that all families receiving prenatal care are educated about newborn screening. As part of the educational process, all state newborn screening programs should maintain and distribute educationally and culturally appropriate information that includes basic information about the use or potential use of the dried blood specimens.

Recommendation 4

If residual blood specimens are to be available for any purpose other than the legally required newborn screening process for which they were obtained, an indication of the parents' awareness and willingness to participate should exist in compliance with federal research requirements

Recommendation 5

It is recommended that the Secretary, HHS provide administrative support and funding to the state programs to develop:

Model consent/dissent processes for the use of residual newborn screening specimens; national data on the utility of any additional consent/dissent processes; model educational programs for the general public; and educational materials for use in such programs with facts about potential uses of residual newborn screening specimens for both consumers and prenatal healthcare providers.

NIH comments

- Urge the Committee to become an advocate for research use by setting forth actual recommendations for States to consider
- Propose voluntary national standards, including provisions for broad research use that each state could consider for adoption

NIH comments

- Recommend that the Secretary provide resources to facilitate a national dialogue with the relevant stakeholders across the states
- Incorporate fuller discussion of education and the two audiences that need to be addressed

NIH comments

- Consider the potential benefit of suggesting the creation of a voluntary national research repository for blood spots into which parents could voluntarily “opt” their children

NIH comments

Pre-meeting discussion of section-by-section comments:

- Policy, ethical and legal issues – add international guidelines for specimen repositories
- Ownership – add case law
- Privacy protections – accept OCR comments

NIH comments

Pre-meeting discussion of section-by-section comments:

- Awareness and education – add discussion of the role of prenatal care providers in educating parents and themselves and cite more published references on the subject

NIH comments

Pre-meeting discussion of section-by-section comments:

- Consent/dissent – work OHRP comments into the paper and add text box explaining anonymized, unidentified, linked with identifiers, identifiable, completely de-identified, private unless decoded and double coded samples